Commonwealth of Virginia Department of General Services Division of Consolidated Laboratory Services Richmond, Virginia

Tuning Fork Laboratory Quality Manual Checklist

Protocol for the Certification of Laboratories Performing Tuning Fork Certification Testing							
Facility Name: Lab ID:							
		Inspection Date:					
ATTACHMENTS Laboratory Equipment List, #6959 or equivalent Laboratory Personnel List, #6960 or equivalent Laboratory Inspection Checklist, #6954							
Item	Relevant Aspect of Protocol	Reference	Υ	N	NA	Comments	
1	Company name, address and contact information	III.B.1					
2	Statements affirming the laboratory's commitments to quality assurance and data integrity.	III.B.2					
3	List of personnel and qualifications	III.B.3					
4	Log of printed names, handwritten initials and signatures of all laboratory personnel authorized to perform tuning fork testing, data review, and certificate notarization.	III.B.4					
5	List of all testing equipment—including manufacturer, model, and serial number—used in the certification procedure.	III.B.5					
6	Information describing the accuracy, range and reproducibility for each instrument and item of support equipment used for the testing and certification of tuning forks.	III.B.6					
7	Corrective Action Policy for response when instrumentation fails to meet fitness for use acceptance criteria.	III.B.7					
8	Schedules for instrument calibration and maintenance including requirements for documenting calibration and maintenance.	III.B.8					
9	Description of circumstances that would require recertification of reference tuning forks (trauma, damage or change in performance).	III.B.9					
Notes							

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Item	Relevant Aspect of Protocol	Reference	Υ	N	NA	Comments	
10	Processes and procedures for ensuring traceability of measurements to nationally recognized standards.	III.B.10					
Description of Procedures being performed, equipment being used, calculations, and examples, adjustments (if any), and references. This information may be included in the Quality Manual or may be a separate Standard Operating Procedure (SOP). At a minimum, the information shall include:							
11	Sample receiving and tracking procedures.	III.B.11.a					
12	Sample Rejection Policy describing the circumstances under which a tuning fork would not be accepted for testing.	III.B.11.b					
13	Procedures for labeling and disposition of rejected tuning forks.	III.B.11.c					
14	Instructions for instrument setup, fitness for use testing and documentation, and acceptance criteria.	III.B.11.d					
The procedure for testing tuning forks submitted by law enforcement agencies for certification and documenting test results:							
15	Reference tuning forks tested prior to beginning testing and at the conclusion of each sample set	III.B.11.e.i					
16	Frequency of oscillation of each reference tuning fork shall be within ±0.5% of that specified by the manufacturer or the most recent independent certification	III.B.11.e.ii					
17	Temperature of the test environment not less than 20°C and not greater than 30°C	III.B.11.e.iii					
18	At least 2 frequency observations recorded and averaged for the calculation of MPH	III.B.11.e.iv					
19	Each page of test documentation dated and initialed by the analyst	III.B.11.e.v					
Review and reporting of test data and calculations:							
20	Process for reviewing and reporting test data and calculations	III.B.11.f					
21	Data review documented with date and initials of reviewer	III.B.11.f.i					
Notes							

Processes for customer notification as well as labeling and disposition of tuning forks that fail the certification testing Data review documented with date and initials of reviewer Final reports notarized Processes for customer notification as well as labeling and disposition of tuning forks that fail the certification testing cian Training: Description of the complete training goals and expected results Learning objectives and expectations upon	III.B.11.f.ii III.B.11.f.ii III.B.11.f.ii III.B.11.g ining process III.B.12.a	and			
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Training goals and expected results		and			
	III B 12 a	anu	supp	orting	g documentation
Learning objectives and expectations upon	D. 12.a				
completion of training	III.B.12.b				
Learning methods and/or activities	III.B.12.c				
Documentation of training	III.B.12.d				
Training effectiveness criteria	III.B.12.e				
Evaluation of training—assessment of documentation against criteria	III.B.12.f				
		nicia	n co	mpet	ence in testing and establishes
Each technician shall perform a minimum of 20 consecutive frequency observations of each reference tuning fork	III.B.13.a.i				
Each technician shall calculate the mean of each data set	III.B.13.a.ii				
The mean frequency of oscillation of each reference tuning fork shall be within ±0.5% of that specified by the manufacturer or the most recent independent certification	III.B.13.b				
d Retention Policy	•		•		
Maintenance logs retained a minimum of three (3) years	III.B.14.a.i				
	Learning methods and/or activities Documentation of training Training effectiveness criteria Evaluation of training—assessment of documentation against criteria Instration of Capability—a procedure for establication and the evaluation of analyst capability—a procedure for establication and the evaluation of analyst capability—a procedure for establication and the evaluation of analyst capability—a procedure for establication and the evaluation of analyst capability—a procedure for establication and technician shall perform a minimum of each reference tuning fork Each technician shall calculate the mean of each data set The mean frequency of oscillation of each reference tuning fork shall be within ±0.5% of that specified by the manufacturer or the most recent independent certification I Retention Policy Maintenance logs retained a minimum of	Learning methods and/or activities Documentation of training Training effectiveness criteria Evaluation of training—assessment of documentation against criteria Instration of Capability—a procedure for establishing technology and the evaluation of analyst capability: Each technician shall perform a minimum of 20 consecutive frequency observations of each reference tuning fork Each technician shall calculate the mean of each data set The mean frequency of oscillation of each reference tuning fork shall be within ±0.5% of that specified by the manufacturer or the most recent independent certification I Retention Policy Maintenance logs retained a minimum of III.B.14.a.i	Learning methods and/or activities Documentation of training Training effectiveness criteria Evaluation of training—assessment of documentation against criteria III.B.12.e Evaluation of Capability—a procedure for establishing technicial ance criteria for the evaluation of analyst capability: Each technician shall perform a minimum of 20 consecutive frequency observations of each reference tuning fork Each technician shall calculate the mean of each data set The mean frequency of oscillation of each reference tuning fork shall be within ±0.5% of that specified by the manufacturer or the most recent independent certification I Retention Policy Maintenance logs retained a minimum of III.B.14.a.i	Learning methods and/or activities Documentation of training Training effectiveness criteria Evaluation of training—assessment of documentation against criteria III.B.12.e Evaluation of Capability—a procedure for establishing technician contained criteria for the evaluation of analyst capability: Each technician shall perform a minimum of 20 consecutive frequency observations of each reference tuning fork Each technician shall calculate the mean of each data set The mean frequency of oscillation of each reference tuning fork shall be within ±0.5% of that specified by the manufacturer or the most recent independent certification I Retention Policy Maintenance logs retained a minimum of III.B.14.a.i	Learning methods and/or activities Documentation of training Training effectiveness criteria Evaluation of training—assessment of documentation against criteria III.B.12.e Evaluation of Capability—a procedure for establishing technician competence criteria for the evaluation of analyst capability: Each technician shall perform a minimum of 20 consecutive frequency observations of each reference tuning fork Each technician shall calculate the mean of each data set The mean frequency of oscillation of each reference tuning fork shall be within ±0.5% of that specified by the manufacturer or the most recent independent certification I Retention Policy Maintenance logs retained a minimum of III.B.14.a.i

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37	Calibration records retained a minimum of three (3) years	III.B.14.a.ii				
38	Sample observation records retained a minimum of three (3) years	III.B.14.a.iii				
39	Training records and Demonstrations of Capability retained a minimum of three (3) years	III.B.14.a.iv				
Docu	mentation practices					
40	All handwritten data shall be recorded in ink	III.B.14.b.i				
41	Changes to laboratory records shall be made with a single strike-out line leaving the original entry visible	III.B.14.b.ii				
42	Changes shall be documented with date and initials of person making the correction	III.B.14.b.iii				
43	Describe procedures for ensuring the security of electronic records	III.B.14.c				
A san	nple copy of a certificate issued to customers s	howing the fo	llowi	ing		
44	Serial number or other unique identifier of the tuning fork	III.B.15.a				
45	The frequency at which the tuning fork was found to oscillate and the corresponding MPH (miles per hour)	III.B.15.b				
46	The designation of the radar frequency band within which the tuning fork is to be used	III.B.15.c				
47	Date of certification testing	III.B.15.d				
48	Signature of the analyst who performed the testing	III.B.15.e				
49	Date, seal and signature of notarization	III.B.15.f				
50	Any additional information required by court systems of the jurisdictions in which laboratory's clients are located	III.B.15.g				
51	Change sheet to allow historic reconstruction of changes to the Quality Manual	III.B.16				
52	Annual review and signature sheet	III.B.17				
Notes						

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